Attorney Docket No.: P-4437-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	GILREATH, MARK	Examiner:	SHAY, DAVID M.
Serial No.:	10/531,692	Group Art Unit:	3769
Filed:	April 18, 2005	Confirmation No.:	1399
Title:	INTUBATION AND IMAGING DEVICE AND SYSTEM		

DECLARATION OF RACHEL BENTOV UNDER 37 C.F.R. § 1.132

1. I was born in 1965 in Boston, Massachusetts.

2. In 1989, I was awarded the degree of Bachelors of Science in Biology from Tel Aviv University, in Tel Aviv, Israel. In 1995, I was awarded the degree of Masters of Science in Biochemistry from Hebrew University, in Jerusalem, Israel.

3. From 1998 through 2000, I was employed by Eitan, Pearl, Latzer & Cohen-Zedek (EPLCZ). During my employment at EPLCZ, I was outside counsel to Given Imaging Ltd. ("Given Imaging") of Yoqneam, Israel on many of its intellectual property matters.

4. From January 2001 until April 2002, I was self employed, during which time I was an outside contractor for EPLCZ and served as outside counsel to Given Imaging through EPLCZ.

5. From April 2002 until early November 2008, I was employed by Given Imaging and, at the time of my voluntary departure in November 2008, held the title Director of Intellectual Property.

6. I am informed that the above-identified application, which is owned by Given Imaging by way of an assignment from the inventor thereof as recorded at the U.S. Patent and Trademark Office ("USPTO") on April 18, 2005 at Reel 017122, Frame 0190, was filed in the USPTO on April 18, 2005 as a national phase application under 35 U.S.C. § 371 of International Patent Application No. PCT/IL2003/000853, which was filed on October 21, 2003 and claimed the benefit of U.S. Provisional Patent Application No. 60/419,558, filed October 21, 2002.

7. I am informed that the USPTO issued an Office Action on October 20, 2009 wherein the Examiner rejected all of pending claims 1-20 under 35 U.S.C. § 102(e) as being anticipated by Mazzei et al. (U.S. Patent No. 6,840,903 or U.S. Patent Application Publ. No. 2003/0181789).

8. I am informed that Mazzei et al., upon which all the rejections depend, was first published under U.S. Patent Appl. Publication No. 2003/0181789 on September 25, 2003, which is after the earliest claimed priority date of Applicants' application, October 21, 2002, but is available as a reference against this application under 35 U.S.C. § 102(e) because Mazzei et al. was filed in the USPTO on March 21, 2002, which is prior to October 21, 2002.

9. I submit this declaration on behalf of Given Imaging under 37 C.F.R. § 1.132 in support of a Response to Office Action and a Declaration of Mark Gilreath Under 37 C.F.R. § 1.131 to show that the subject matter of the pending claims of this application was conceived of by the inventors hereof prior to March 21, 2002.

10. As part of my responsibilities as out-side counsel to Given Imaging through EPLCZ, I prepared and assisted in the preparation of patent applications for Given Imaging. In late 2001, the inventor and attorneys at EPLCZ, including myself, held a meeting wherein the conception and embodiments of this invention were discussed. In February 2002, based upon disclosure from the inventor, I personally and directly participated in the preparation and revision of a provisional patent application for Given Imaging concerning the invention that is the subject of this patent application. Successive versions of this draft application were saved on my personal computer in the electronic file folder for that invention, the first of which was saved on February 17, 2002, and the last of which was saved on May 9, 2002.

11. In April 2002, I joined Given Imaging as patent counsel. Because Given Imaging had not previously had an in-house patent counsel and did not have a database of documents relating to patent applications filed on its behalf, I had all the patent files relating to patent applications filed by EPLCZ on behalf of Given Imaging that were on my personal computer copied onto the Given Imaging computer system. In order to preserve the integrity of the documents copied from my computer, I made it a practice not to modify and save any of those documents except as new documents. Accordingly, virtually all documents that were copied from my personal computer now exist on the Given Imaging computer database in

their original form and with the exact same file names and last modification dates as those documents had on my personal computer.

12. Attached hereto as Exhibit A is a copy of a snapshot of the directory from my "old documents" directory at Given Imaging relating to this patent application. This directory shows documents relating to this patent application entitled "intubation" that were copied from my personal computer at the time of that I joined Given Imaging, all of which have the exact same file names as those documents I had on my computer, which indicates that these documents have been unmodified since they were copied from my computer. This directory shows draft patent applications on this subject matter beginning February 2002 and continuing through May 2002. Specifically, the directory shows a draft patent application named "intubation-draft1.doc" saved on February 17, 2002; a draft patent application named "intubation-draft1 with comments.doc" saved on February 18, 2002; a draft patent application named "intubation3.doc" saved on April 15, 2002; a draft patent application named "intubation3rbcomment.doc" saved on April 17, 2002; a draft patent application named "intubation3CP1.doc" saved on April 21, 2002; a draft patent application named "intubation6.doc" saved on May 5, 2002; and a draft patent application named "intubation6rb.doc" saved on May 9, 2002.

13. Attached hereto as Exhibit B is a printed-out copy of the draft patent application named "intubation-draft1.doc" that was saved on February 17, 2002 in the directory referred to above.

I declare under penalty of perjury that all statements made herein are based upon my own knowledge and believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of any patent that may be issued from the above-identified patent application.

Rachel Bentov

Rachel Bentov

Date: February 15, 2010

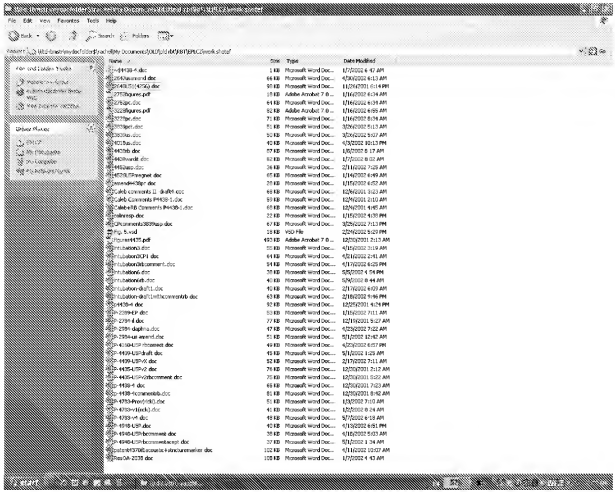

EXHIBIT A

INTUBATION TOOL HAVING AN IMAGING UNIT

FIELD OF THE INVENTION

The present invention relates to the field of medical devices, more specifically to a combination of endotracheal intubation device such as laryngoscope and an imaging unit operates in-vivo.

BACKGROUND OF THE INVENTION

Endotracheal intubation is a very common medical procedure mainly directed to open a closed larynx by inserting laryngoscope through the larynx following by the insertion of endotracheal tube thus enabling air supply to the patient. Endotracheal intubation is a life saving procedure performed in emergency cases thus the ability to intubate a patient rapidly is highly important.

In many patients, intubation is particularly hard to perform due to morphological anomalies, such as a large tongue, excessive soft tissue, or tracheal displacement. These morphological anomalies make it difficult to visualize the posterior pharyngeal area, larynx and cords, thus cause difficulties in intubation. In emergency medical situations, attempts to intubate such persons is difficult, time consuming, and often meets with failure.

To overcome this problem intubation devices including illumination and visualizing means for illuminating and visualizing the pharynx, larynx, trachea and associated structures during intubation were developed.

U.S. Pat. No. 4,982,729 and 5,261,392, issued to Wu, discloses a laryngoscope comprising a blade and an integral handle having an enclosed cavity which receives a fiberoptic bundle having illuminating and viewing fibers. An eyepiece is connected to view the image from the viewing fiberoptic bundle.

U.S. Pat. No. 5,363,838 issued to George, directed to an intubating scope with an auxiliary fiber optic camera connected to an external electronic

viewing screen. The intubating scope is disposed within an endotracheal tube, which is inserted into the airway after a laryngoscope blade has been inserted and used to open the airway. Accordingly, the fiber optic scope is useful for guiding the endotracheal tube further into the larynx and trachea after a laryngoscope has been inserted and utilized to open the airway.

U.S. Pat. No. 4,901,708, issued to Lee, discloses a viewing laryngoscope comprising a blade having a pair of fiberoptic bundles. One bundle transmits light to the distal end of the blade, and the other bundle is optically coupled to a lens for viewing of the area adjacent the distal end of the blade. The device does not enable remote simultaneous viewing of the airway during insertion of the blade.

U.S. Pat. No. 6,123,666 issued to Wrenn, discloses a laryngoscope equipped with a fiberoptic scope for enabling simultaneous remote observation of the airway and associated structures during insertion of the laryngoscope blade. The laryngoscope includes a blade member configured for attachment to a handle, a conduit positioned adjacent the blade member for housing a fiberoptic scope. The fiberoptic scope includes fibers for illuminating an area adjacent a distal end of the blade and viewing fibers for transmitting a visual image of the illuminated area to a remote viewing system.

SUMMARY OF THE INVENTION

To be completed after claims is finalized.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Figure 1 is a schematic illustration of the intubation device in accordance with an embodiment of the invention; and

Figure 2 is a schematic illustration of the imaging unit in accordance with an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In the following description, various aspects of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the present invention. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details presented herein. Furthermore, well known features may be omitted or simplified in order not to obscure the present invention.

Embodiments of the present invention relate to endotracheal intubation device such as a laryngoscope, comprising a wireless disposable imaging unit allowing in vivo continuous visualization during the insertion of the laryngoscope and the endotracheal tube.

A schematic illustration of the device, in accordance with an embodiment of the invention, is presented in Fig. 1. The endotracheal intubation device 10 comprises a laryngoscope 20, an imaging unit 30 attached to laryngoscope 20 and a display unit 50. Laryngoscope 20 comprises a blade 22 having a proximal end 23, a distal end 21 and a handle 24 which is preferably attached to the proximal end 23 of laryngoscope 20. Laryngoscope 20 may be of any kind existing including, for example, laryngoscope comprising a tube for air passage or for insertion of tools.

The operation of the laryngoscope 20 may be viewed by the images captured in vivo by imaging unit 30. Imaging unit 30 is preferably located near or at the distal end 21 of blade 22, such that the internal organ at the site of operation may be imaged and viewed in display system 50, simultaneously in the real time operation of laryngoscope 20.

Reference in now made to Figure 2 which is an illustration of the in-vivo imaging unit 30. Imaging unit 30 may be disposable thus prevents the need of sterilization between uses and wireless thus enable comfortable and flexible use. The imaging unit 30 preferably comprises an imager 34 (preferably a CMOS camera) and an illumination source 36 (preferably white LEDs), both situated behind a dome shaped optical window 31. The imaging unit further comprises a transmitter 33 and an antenna 35 that transmit signals from the imager 34 to the display system 50 and a power supplier 37 (preferably a silver

oxide battery), for supplying the electric power required for the operation of the imaging unit 30. Other imaging units may be used.

Imager 34 may be for example a CCD, an active or passive CMOS imaging chip and may generate digital or analog signals. Preferably, imager 34 is a single chip imager similar to the CMOS image sensor (Camera on Chip) designed by Photobit Inc. of California, USA, with integrated active pixel and post pixel circuitry. The imaging unit may by similar to that described in WO 00/76391 or the imaging unit described in US Patent Number 5,604,531 both of which are assigned to the common assignee of the present invention and both of which are hereby incorporated by reference, or as described in US application number 09/800,470, which is attached herein as Appendix A; other imaging units may be used.

It will be appreciated that a plurality of CMOS imaging cameras may be used in the device and system of the invention. Each CMOS imaging camera may include its own optical system and either one or more illumination sources, in accordance with specific requirements of the device or system.

Both CMOS imager and LED are low power components such that they may be powered by a battery thus do not require wire connection to a power supply system. In one embodiment the battery may be incorporated within imaging unit 30 at the distal end 21 of laryngoscope blade 22.

In one embodiment imaging unit 30 is a one part imaging unit as described hereinabove. In alternate embodiment imaging unit 30 is a two part imaging unit wherein the first part situated at the distal end of blade 22 and the second part situated at the handle. The first and the second parts are connected via electric wires. The first part of the two part imaging unit comprises imager 34 (preferably a CMOS camera) and illumination source 36 (preferably white LEDs) both situated behind a dome shaped optical window 31. The second part comprises a transmitter 33 and an antenna 35 that transmit signals from the imager 34 to an external receiving system and a power supplier 37 (preferably a silver oxide battery). This embodiment allows further miniaturizing of the first part of imaging unit 30 located at the distal end of blade 22.

Display unit 50, located outside of the patient body, comprises a receiver, a processor and a screen. The display unit 50 receives signals from imager 34 located in imaging unit 30 and process the signals to an image output

displayed on a screen. The display unit 50 preferably comprises a receiver 52 to receive the signals, a processor 54 which is preferably a computer, for processing the received signals and a screen 56, which is preferably a computer screen, for enabling the view of the images. The display unit 50 is typically located outside the patient body while the imaging unit 30 is typically located in-vivo, and transmitting the signals to the display unit.

Transmission of signals from the CMOS imager 34 may be effected wireless, using various digital or analog modulation techniques. For example transmission of a digital image over a radio channel may use an FSK (Frequency Shift Keying) modulation technique.

A wireless communication is exist between imaging unit 30 and an external power supply system and between imaging unit 30 and the display system 50 thus allowing a convenient and flexible maneuvering of endotracheal intubation device 10 with simultaneous in-vivo viewing.

Further, the device has the benefit of performing endotracheal intubation procedures while viewing the patient in-vivo, in the field. This is particularly intended for emergency cases such as obstructed airway where an intubation procedure is required.

Embodiment of an endotracheal intubation device 10 for the emergency treatment in field includes endotracheal intubation device 10, imaging unit 30, and display system 50. The display system 50 comprises the receiver 52 and a processor 54 which is preferably a portable computer (e.g., a PC or palm-top computer) thus, preferably allow the processing of the information and the viewing of the in-vivo images without a connection to an external power supply system.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Alternate embodiments are contemplated which fall within the scope of the invention.

CLAIMS

1. Apparatus for performing intubation procedure comprising:

a laryngoscope;

a one part imaging unit wherein said one part imaging unit attached to laryngoscope for enabling imaging a site in-vivo; and

a display system for receiving signals from said one part imaging unit and process the signals to an image output.

2. The apparatus of claim 1 wherein said laryngoscope comprises of a handle and a blade wherein said blade having a distal end and a proximal end.

3. The apparatus of claim 2 wherein said handle is attached to the proximal end of said blade.

4. The apparatus of claim 1 wherein said imaging unit is one part imaging unit comprising:

an imaging camera;

at least one illumination source for illuminating a site in vivo;

an optical system for imaging the site in vivo onto the imaging camera;

a battery; and

a transmitter for transmitting video output of the imaging camera.

5. The apparatus of claim 4 wherein said imaging camera includes at least a CMOS camera.

6. The apparatus of claim 4 wherein said illumination source includes at least a white LED.

7. The apparatus of claim 4 wherein said optical system comprises an aspherical focussing lens.

8. The apparatus of claim 4 wherein said CMOS imaging camera transmit said video output wirelessly to said receiving system.

9. The apparatus of claim 4 wherein said transmitter transmits the image over a radio channel using a frequency shift keying modulation technique.

10. The apparatus of claim 1 wherein said receiving system is located outside a patient.

11. The apparatus of claim 1 wherein said display system comprises a receiver for receiving images from said imaging unit and a processor for processing said images received in said receiver and a screen for viewing the processed images.

12. The display system of claim 11 wherein said receiver and said processor are constructed as one unit wherein said receiver is incorporated in said processor.

13. The receiving system of claim 11 wherein said receiver and said processor are constructed as two separate parts connected by a wire.

14. The apparatus of claim 4 wherein said one part imaging unit attached to said laryngoscope.

15. The apparatus of claim 4 wherein said one part imaging unit attached to the distal end of said laryngoscope blade.

16. Apparatus for performing intubation procedure comprising:

a laryngoscope;

a two part imaging unit wherein said two part imaging unit attached to laryngoscope for enabling imaging a site in-vivo; and

a display system for receiving signals from said two part imaging unit and process the signals to an image output

17. The apparatus of claim 16 wherein said two part imaging unit is a having a first and a second part wherein said first part comprising:

an imaging camera;

at least one illumination source for illuminating a site in vivo; and

an optical system for imaging the site in vivo onto the imaging camera;

and a second part comprising:

a battery; and

a transmitter for transmitting video output of the imaging camera.

18. The apparatus of claim 17 wherein said first part attached to the distal end of said laryngoscope blade.

19. The apparatus of claim 7 wherein said second part attached to said laryngoscope handle.

20. The apparatus of claim 7 wherein said first part and said second part are connected via electric wires.

~~10.~~21. The apparatus of claim 17 wherein said imaging camera includes at least a CMOS camera.

~~11.~~22. The apparatus of claim 17 wherein said illumination source includes at least a white LED.

~~12.~~23. The apparatus of claim 17 wherein said optical system comprises an aspherical focussing lens.

~~13.~~24. The apparatus of claim 17 wherein said CMOS imaging camera transmit said video output wirelessly to said receiving system.

~~14.~~25. The apparatus of claim 17 wherein said transmitter transmits the image over a radio channel using a frequency shift keying modulation technique.

~~15.~~26. The apparatus of claim 17 wherein said receiving system is located outside a patient.

~~16.~~27. The apparatus of claim 17 wherein said receiving system comprises a receiver for receiving images from said imaging unit and a processor for processing said images received in said receiver and allow a view of the processed images.

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~~17.~~28. The receiving system of claim 27 wherein said receiver and said processor are constructed as one unit wherein said receiver is incorporated in said processor.

~~18.~~29. The receiving system of claim 27 wherein said receiver and said processor are constructed as two separate parts connected by a wire.

30. A method for performing in-vivo intubation procedures comprising the steps of:

inserting a laryngoscope and an imaging unit attached to said laryngoscope;

obtaining images of the site in-vivo;

maneuvering the laryngoscope according to the obtained images.